

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:
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Date of mailing
(day/month/year) **28 DEC 2006**

Applicant's or agent's file reference

FOR FURTHER ACTION

See paragraph 2 below

DRE-0152

International application No.

International filing date (day/month/year)

Priority date (day/month/year)

PCT/US04/11845

16 April 2004 (16.04.2004)

16 April 2003 (16.04.2003)

International Patent Classification (IPC) or both national classification and IPC

IPC(7): A61B 05/00 and US Cl.: 600/369, 368, 309

Applicant

DREXEL UNIVERSITY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of completion of this opinion

30 September 2006 (30.09.2006)

Authorized officer

Navin Natnithithadha

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/11845

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/11845

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims <u>14 and 15</u>	YES
	Claims <u>1-13 and 16</u>	NO
Inventive step (IS)	Claims <u>14 and 15</u>	YES
	Claims <u>1-13 and 16</u>	NO
Industrial applicability (IA)	Claims <u>1-16</u>	YES
	Claims <u>NONE</u>	NO

2. Citations and explanations:

Claims 1-13 and 16 lack novelty under PCT Article 33(2) as being anticipated by Thomas et al, US 5,119,819 (hereinafter referred to as D1).

As to claims 1-13 and 16, D1 teaches an acoustic blood analyzer for analyzing changes in blood glucose, including a probe 10, acoustic transducers 12 for transmitting and receiving acoustic energy to and from a blood sample; and a cannula 16.

Claim 14 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for measuring specific coagulation cascades steps, activation of plasma factors, or platelet function by analyzing the blood sample with an acoustic blood analyzer.

Claim 15 meets the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a method for identifying, diagnosing and monitoring subjects at high risk for blood clots and excessive bleeding comprising analyzing a blood sample using an acoustic blood analyzer.

Claims 1-16 meet the criteria set out in PCT Article 33(4), and thus meeting industrial applicability because the subject matter claimed can be made or used in industry.